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In the Supreme Court of the United States

OCTOBER TERM, 1997

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,
PETITIONER

v.

SARAH KERNATS, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE APPELLATE COURT OF ILLINOIS

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

SETH P. WAXMAN
Solicitor General

FRANK W. HUNGER
Assistant Attorney General

DOUGLAS N. LETTER
THOMAS M. BONDY
Attorneys

Department of Justice
Washington, DC 20530-0001
(202) 514-2217

QUESTION PRESENTED

Whether the Medical Device Amendments of 1976 (MDA), which create a federal program for regulating medical devices and prohibit the States from imposing safety requirements that are "different from, or in addition to," federal requirements, 21 U.S.C. 360k(a), preempt a State's general common law remedies for injury from defective products.

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This brief is filed in response to the Court's order inviting the Solicitor General to file a brief expressing the views of the United States.

STATEMENT

Petitioner seeks review of a decision of the intermediate Appellate Court of Illinois arising from three separate tort suits in which respondents allege that they were injured by a medical device manufactured by petitioner. Petitioner moved for summary judgment in each case on the ground that a federal statute, the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, preempts respondents' claims. The trial court in each case granted petitioner's motion for summary judgment. Pet. App. 25-32. The Appellate Court of Illinois consoli-

dated respondents' appeals, reversed the trial court judgments, and remanded the cases for trial. *Id.* at 1-19.

1. The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), 21 U.S.C. 301 *et seq.*, empowers the Food and Drug Administration (FDA) to regulate a wide variety of medical and non-medical products. The MDA supplements the FDCA's original provisions by creating a federal program to enhance "the safety and effectiveness of medical devices intended for human use" (90 Stat. 539 (Preamble)). See generally *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240, 2245-2246 (1996). The MDA authorizes the FDA to undertake specified review, approval, and regulatory activities for medical devices, which include instruments, implants, and similar articles that are intended to affect the structure or function of the body or for use in medical applications. See 21 U.S.C. 321(h) (defining "device"), 360c-360*l* (regulatory program).

a. The MDA provides for the classification of medical devices into three categories based on the risk that they pose to the public. 21 U.S.C. 360c(a). Class I devices are articles, such as tongue depressors and sunglasses, that present no unreasonable risk of illness or injury. See 21 C.F.R. 880.6230, 886.5850. The FDA subjects those devices to limited regulation through the use of "general controls," 21 U.S.C. 360c(a)(1)(A), which involve measures such as general labeling and manufacturing practices requirements. See, *e.g.*, 21 U.S.C. 352, 360j(f). Class II devices are articles, such as breathing frequency monitors and infusion pumps, for which "general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. 360c(a)(1)(B); see 21 C.F.R. 868.2375, 880.5725. The MDA subjects those devices to "special controls." 21 U.S.C. 360c(a)(1)(B). In the case of both Class I and Class II devices, the MDA does not require advance FDA approval before the device may be marketed. The maker usually

must comply, however, with the FDA's registration requirements and provide the agency with a "premarket notification" before distributing the device. See 21 U.S.C. 360(b) and (k).

Class III devices are articles, such as cardiac pacemakers and intraocular lenses, that present "a potential unreasonable risk of illness or injury." 21 U.S.C. 360c(a)(1)(C); see 21 C.F.R. 870.3610, 886.3600. In general, the makers of those articles are subject not only to general and certain special controls, but also to the FDA's "premarket approval" (PMA). See 21 U.S.C. 360c(a)(1)(C), 360e(a). An application for PMA must contain detailed supporting information, including full reports of any clinical investigations respecting the safety and effectiveness of the device, and a complete description of the device's components and method of manufacture. See 21 U.S.C. 360e(c). The FDA will approve the device unless it finds that the applicant has failed to provide reasonable assurance that the device is safe and effective for its intended use or that the applicant has failed to satisfy general manufacturing and labeling requirements. See 21 U.S.C. 360e(d); see also 21 C.F.R. Pt. 814.

b. The MDA provides that, in certain circumstances, a Class III device may be made available for use without obtaining a PMA. Of greatest practical importance, a maker may be entitled to postpone the PMA process if it proposes to market a Class III device that is substantially similar to a device that was on the market before the MDA's enactment and for which premarket approval is not required. The MDA contains a "grandfather" clause that allows continued marketing of devices that were on the market before the MDA's enactment until the FDA initiates and completes a rulemaking procedure requiring the submission of a PMA for the device. See 21 U.S.C. 360e(b)(1)(A). To prevent the "grandfathered" makers from monopolizing the market, the MDA provides

that other makers may distribute similar devices upon a showing through the general premarket notification process, 21 U.S.C. 360(k), that the devices are "substantially equivalent." 21 U.S.C. 360e(b)(1)(B). That procedure is known as the "Section 510(k) process," referring to the section of the FDCA codified at 21 U.S.C. 360(k). See *Medtronic*, 116 S. Ct. at 2247.

A maker may also defer the PMA process if it qualifies for an "Investigational Device Exemption" (IDE). Under that exemption, the FDA may approve an application for use of the device in clinical investigations to study its potential safety and effectiveness. See 21 U.S.C. 360j(g); 21 C.F.R. Pt. 812. Generally speaking, the FDA has provided by regulation that it may grant an IDE if it determines, based on the application, that the risks to the subjects of the investigations are outweighed by their anticipated benefits and the importance of the knowledge to be gained. 21 C.F.R. 812.30(b)(4).

c. The MDA contains a provision expressly addressing the question of preemption of state law. Section 521(a), 21 U.S.C. 360k(a), states:

> **(a) General rule**
>
> Except as otherwise provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Subsection (b) then provides that a State or political subdivision thereof may apply for an exemption for a require-

ment that would otherwise fall within the scope of Section 360k(a). See 21 U.S.C. 360k(b).

2. This Court addressed Section 360k's preemptive effect in *Medtronic*. The plaintiffs, husband and wife, alleged that the wife was injured by a defective pacemaker, a Class III device. The FDA had cleared the device for distribution on the basis, noted above, that the product was "substantially equivalent" to a pre-MDA device. The plaintiffs sought damages for their injuries under state tort law. They alleged that the manufacturer had negligently designed, built, and labeled the device and also sought recovery under a state law theory of strict product liability. The manufacturer contended that the MDA preempted the plaintiffs' claims because Section 360k prohibits a State from imposing a safety "requirement" that is "different from, or in addition to," any MDA requirement. The Court rejected the manufacturer's argument.[1]

a. At the outset of its analysis, the Court recognized the familiar presumption that the States retain their historic police powers unless Congress expresses a "clear and manifest purpose" to supersede those powers. *Medtronic*, 116 S. Ct. at 2250. The Court also acknowledged the "oft-repeated" observation that congressional purpose "is the ultimate touchstone" in every preemption case and that "a fair understanding of congressional purpose" may be discerned not only from the text of the statute, "but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Id.* at 2250-2251 (emphasis deleted).

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[1] Justice Stevens wrote an opinion in which Justices Kennedy, Souter, and Ginsburg joined in full. 116 S. Ct. at 2245-2259. Justice Breyer concurred in parts I through III, V, and VII of Justice Stevens' opinion and concurred in the judgment. *Id.* at 2259-2262. Justice O'Connor, joined by the Chief Justice and Justices Scalia and Thomas, concurred in part and dissented in part. *Id.* at 2262-2264.

b. Turning to the maker's specific arguments, the Court first evaluated whether Section 360k preempted state law claims alleging the manufacturer had defectively designed the pacemaker. 116 S. Ct. at 2254-2255. It noted that, while the MDA required the manufacturer to provide the FDA with premarket notification, and the FDA may have conducted the premarket notification process "with a concern for the safety and effectiveness of the device," the FDA "did not 'require' Medtronic's pacemaker to take any particular form for any particular reason." *Id.* at 2254. The Court accordingly concluded that the manufacturer's compliance with the PMA process "did not preempt the [plaintiffs'] design claims." *Id.* at 2255; accord *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part) (Section 510(k) process "places no 'requirements' on a device" and therefore does not preempt defective design claim).

The Court next examined whether Section 360k preempted state law claims that the manufacturer had violated FDA requirements. 116 S. Ct. at 2255-2256. It concluded that state law claims premised on a violation of FDA requirements do not subject the manufacturer to requirements that are "different from, or in addition to," the federal requirements. *Id.* at 2255. The Court noted that the FDA's interpretive regulations "expressly support the conclusion that § 360k 'does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act,'" *id.* at 2256 (quoting 21 C.F.R. 808.1(d)(2)), and it observed that the FDA's views on the scope of Section 360k's preemptive effect are entitled to "substantial weight," *ibid.*; see also *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment).[2]

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[2] Justice O'Connor agreed with the majority that state law claims based on violations of federal requirements are not preempted, but

The Court also examined whether Section 360k preempted state law claims based on negligent manufacturing and labeling. 116 S. Ct. at 2256-2258. The Court recognized that the FDA had developed regulations that set out general "requirements" for manufacturing and labeling medical devices. *Id.* at 2256. It concluded, however, that Section 360k does not mandate preemption unless, as the FDA had suggested in its interpretive regulations, the federal requirements impose specific requirements on a particular medical device. *Id.* at 2257 (citing 21 C.F.R. 808.1(d)). The Court concluded that the "entirely generic" federal manufacturing and labeling requirements did not provide a basis for preemption of the non-specific state common law duties at issue in that case. *Id.* at 2258. In his separate opinion, Justice Breyer, agreeing with Justice O'Connor's opinion for four Justices (see *id.* at 2262-2263), concluded that, ordinarily, insofar as the MDA preempts a state requirement embodied in a state statute or regulation, it also preempts a similar state requirement that takes the form of a standard of care or behavior imposed by state tort law, *id.* at 2259-2260; but he concurred in the Court's holding that the federal manufacturing and labeling requirements were not sufficiently "specific" to trigger preemption, *id.* at 2260-2261.[3]

3. Petitioner manufactures and sells a "chorionic villus sampling" (CVS) catheter, a Class III device used to sample fetal tissue to detect genetic abnormalities during the early stages of pregnancy. From 1984 to 1990, petitioner made the CVS catheter available for use through an

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disagreed with the majority's reliance on the FDA regulations interpreting the Act's preemption provision. 116 S. Ct. at 2263, 2264.

[3] The separate opinion of Justice O'Connor did not agree with the majority's conclusion that, as construed in the FDA regulations, only "specific" federal requirements trigger preemption under Section 360k(a). See 116 S. Ct. at 2263, 2264.

exemption for use under the MDA's IDE provisions. In 1990, petitioner completed the PMA process. Pet. App. 2-3, 6 n.3. In the three cases at issue, respondents alleged that the CVS catheter had caused prenatal injuries and sought damages under state law theories of strict product liability, breach of express and implied warranties, and common law negligence. In two of those cases, the medical procedures took place while the IDE was in effect. In the third case, the medical procedure took place after petitioner had received the PMA. In all three cases, the district court granted petitioner's motion for summary judgment, concluding that, under Section 360k, the federal regulatory process had resulted in preemption of respondents' state law tort claims. *Id.* at 25-32.

The Appellate Court of Illinois consolidated respondents' appeals, reversed the judgments, and remanded the cases for trial. Pet. App. 1-19. The court recognized that "the facts in the present case are different from those in *Medtronic* because the medical device here underwent rigorous PMA scrutiny." *Id.* at 13. Although the court observed that this Court did not consider in *Medtronic* whether the PMA review process is sufficiently concrete so as to constitute a "specific" requirement having preemptive force, it held, following a number of pre-*Medtronic* appellate decisions, that the PMA process is a specific federal requirement. *Ibid.* The Court concluded, however, that the generic state law tort duties that petitioner had allegedly breached were not requirements specifically developed with respect to medical devices, and therefore were not preempted. *Id.* at 13-14.

The Appellate Court of Illinois explained its reasoning as follows:

> Here, [respondents'] common-law claims based on the manufacture of the CVS catheter, the failure to warn, and inadequate instructions, are also "general

> obligations" applicable to all manufacturers and, under the holding in *Medtronic*, are not requirements specifically established for medical devices. Therefore, they are not preempted under the MDA. [Respondents'] claims based on defective design and inadequate testing allege that defendant defectively designed and failed to adequately test the CVS catheter. Although these allegations relate to the specific medical device at issue here, they arise, nevertheless, from general duties applicable to every manufacturer.

Pet. App. 14. For similar reasons, the court rejected petitioner's argument that the MDA preempts state statutory law claims based on an implied warranty of merchantability and fitness. *Id.* at 16. It also rejected petitioner's assertion of preemption with respect to express warranty claims, noting that those claims are based on "[petitioner's] own express representations" and are not state "requirements" within the meaning of Section 360k. *Id.* at 18.

The Supreme Court of Illinois denied discretionary review. Pet. App. 20, 23.

DISCUSSION

Petitioner contends that the Appellate Court of Illinois has incorrectly applied this Court's decision in *Medtronic*, which interpreted the preemptive effect of Section 360k. As petitioner correctly points out, the state court's decision in this case involves an issue of substantial importance that has divided the lower courts. This Court's review is unwarranted, however, in this case. First, as a threshold matter, a proper jurisdictional basis is lacking because the judgment is not final within the meaning of 28 U.S.C. 1257. Second, although we disagree with the reasoning of the Appellate Court of Illinois, the judgment below is correct. Third, the FDA will publish for public comment a proposed interpretive rule on the statutory provision at issue. Because this Court's decision in

Medtronic is relatively recent, and the FDA is providing an interpretive rule on the subject, there is no urgent need for the Court to revisit the question of Section 360k's preemptive effect at this time.

1. This Court lacks jurisdiction to review the judgment of the Appellate Court of Illinois because that judgment is neither final in a strict sense nor included within one of the exceptions to strict finality recognized by this Court. Petitioner invokes this Court's jurisdiction under 28 U.S.C. 1257. By its terms, that provision encompasses "[f]inal judgments or decrees rendered by" state courts. Thus, as a general rule, interlocutory state court decisions are not reviewable under Section 1257, and state court rulings fall within the literal meaning of this provision only if they conclusively resolve the litigation and represent "the final word of a final court." *Jefferson* v. *City of Tarrant*, No. 96-957 (Dec. 9, 1997), slip op. 5; *Market St. Ry.* v. *Railroad Comm'n*, 324 U.S. 548, 551 (1945); see, *e.g.*, *Cox Broadcasting Corp.* v. *Cohn*, 420 U.S. 469, 476-487 (1975); *Urie* v. *Thompson*, 337 U.S. 163, 171-172 & n.10 (1949); see also Robert Stern, Eugene Gressman, Stephen Shapiro & Kenneth Geller, *Supreme Court Practice* 92-111 (7th ed. 1993).

The judgment of the Appellate Court of Illinois is not final in that strict sense. The court's interlocutory ruling reverses the trial courts' grants of summary judgment and remands for further proceedings. Petitioner may well prevail on some or all claims on remand. And if the ultimate result of the litigation is unfavorable to petitioner in any respect, petitioner may at that time seek review of the preemption issue in this Court, based on a more fully developed record and any further rulings by the state courts on preemption.

Adhering to the view that finality should be given "a 'practical rather than a technical construction,'" *Cox Broadcasting*, 420 U.S. at 478 n.7 (quoting *Cohen* v.

Beneficial Indus. Loan Corp., 337 U.S. 541, 546 (1949)), this Court has recognized four categories of cases that constitute exceptions to strict finality under 28 U.S.C. 1257. *Cox Broadcasting*, 420 U.S. at 476-487; *Duquesne Light Co.* v. *Barasch*, 488 U.S. 299, 306 (1989). The first three categories consist of situations, respectively, in which: (1) the federal issue is conclusive or the outcome on remand is pre-ordained; (2) the federal issue will survive and require decision regardless of the outcome of proceedings on remand; and (3) the federal issue cannot be reviewed after the conclusion of the proceedings on remand. *Cox Broadcasting*, 420 U.S. at 479-481. As in *Flynt* v. *Ohio*, 451 U.S. 619 (1981) (per curiam), "it is not even arguable that the judgment involved here falls within any of the first three categories identified in the *Cox* opinion." *Id.* at 621.

The fourth category consists of situations that satisfy two requirements. First, the state court judgment must represent the final word within the state court system on a federal issue, "with further proceedings pending in which the party seeking review here might prevail on the merits on nonfederal grounds, thus rendering unnecessary review of the federal issue by this Court, and where reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action." *Cox Broadcasting*, 420 U.S. at 482-483. Second, "a refusal immediately to review the state-court decision" must risk "seriously erod[ing] federal policy." *Id.* at 483.

In the United States' view, the judgment of the Appellate Court of Illinois does not fall within the fourth *Cox* category. We may assume that, if the judgment petitioner seeks to have reviewed were the judgment of the Illinois Supreme Court, it would satisfy the first prong of the two-part test, because the federal issues would have been finally resolved (but see pages 17-18, *infra*) and because petitioner might prevail on remand by establish-

ing that it is not liable under the state law standard. Here, however, petitioner seeks review of the decision of an intermediate appellate court. That judgment may not represent the final word in the state court system on the preemption issue because, although the Illinois Supreme Court denied discretionary review at this interlocutory stage, it might later choose to grant review of the federal questions on appeal from a final judgment. But see *Belknap, Inc.* v. *Hale*, 463 U.S. 491, 497 n.5 (1983) (finding jurisdiction without specifically addressing status of judgment below as that of intermediate appellate court). There is no need to decide whether an intermediate state appellate court judgment is a "final judgment" for purposes of the fourth *Cox* exception, however, because petitioner falls short of establishing, under the second prong of the fourth exception, that postponing review will likely erode an important federal policy. In this case, an argument that the situation falls within the fourth category, "although not frivolous, is unsound." *Flynt*, 451 U.S. at 621.

This Court has most frequently found a potential erosion of federal policy when the state court ruling has restricted the exercise of a fundamental constitutional right.[4] This case, however, does not involve such a situation. The Court has also exercised jurisdiction when the state court ruling could undermine a federal statutory policy, particularly when the policy was furthered by restricting the forum in which the merits of a dispute

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[4] See *Fort Wayne Books, Inc.* v. *Indiana*, 489 U.S. 46, 54-56 (1989) (freedom of the press); *National Socialist Party of America* v. *Village of Skokie*, 432 U.S. 43, 44 (1977) (per curiam) (freedom of speech); *Cox Broadcasting*, 420 U.S. at 485-487 (freedom of the press); *Miami Herald Publishing Co.* v. *Tornillo*, 418 U.S. 241, 247 n.6 (1974) (same); *Calder* v. *Jones*, 465 U.S. 783, 788 n.8 (1984) (due process limitations on personal jurisdiction); *Shaffer* v. *Heitner*, 433 U.S. 186, 195 n.12 (1977) (same).

could be resolved.[5] This case, however, does not present a comparable threat to a congressional policy.

First, as this Court noted in *Medtronic*, the central purpose of the MDA is "to provide for the safety and effectiveness of medical devices intended for human use," 116 S. Ct. at 2245 (quoting 90 Stat. 539 (Preamble)), in order to "safeguard the health of the American public," H.R. Rep. No. 853, 94th Cong., 2d. Sess. 12 (1976). Allowing respondents' tort suits to proceed will in no way undermine that interest in protecting consumers and promoting public health. On the contrary, allowing the suits to go forward should, as a general matter, promote those very interests by deterring manufacturers from distributing defective or unreasonably dangerous medical devices.

Second, to the extent that Section 360k of the MDA expresses a federal policy to preempt state requirements respecting the safety and effectiveness of medical devices, that concern is "related more to the risk of *additional* federal and state regulation rather than the danger of preexisting duties under common law." *Medtronic*, 116 S. Ct. at 2253. There is no inherent conflict between regulation of devices by the FDA (including the IDE and PMA processes) and state law tort claims; the Federal Act does not establish a rule of primary jurisdiction to adjudicate individual disputes. Moreover, as we explain in greater detail below, Section 360k does not, on the present record, preempt respondents' common law tort claims. Accord-

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[5] See *Belknap*, 463 U.S. at 497 n.5 (resolving labor-management disputes before the NLRB); *Local No. 438 Construction & General Laborers' Union* v. *Curry*, 371 U.S. 542, 550 (1963) (same); *Southland Corp.* v. *Keating*, 465 U.S. 1, 6-8 (1984) (resolving contractual issue through arbitration under Federal Arbitration Act rather than through adjudication); *Mercantile Nat'l Bank* v. *Langdeau*, 371 U.S. 555, 557-558 (1963) (limiting venues within which suits against national banks may be brought).

ingly, allowing respondents' suits to proceed will not erode the federal policy expressed in the MDA.[6]

2. Petitioner asserts that, because it secured an IDE and PMA for the device at issue, it should not be subject to product liability claims under state law. That contention is incorrect. In the FDA's view, as reflected in its notice of proposed rulemaking for the issuance of an interpretive rule under Section 360k (see App., *infra*, 1a-18a), the agency's decision to grant an IDE and PMA for the device at issue here did not establish specific federal requirements within the meaning of Section 360k. Like its review of the premarket notification in *Medtronic*, the FDA's review in this case established only that the manufacturer had complied with the applicable federal minimum standards for use and marketing. As this Court indicated in *Medtronic*, Section 360k will generally result in preemption of state tort claims only if the federal government has imposed specific requirements on a particular medical device and the state common law imposes a requirement on the same device that is "different from, or in addition to," the federal requirement. See 116 S. Ct. at 2257-2258. In these circumstances, the Appellate Court of Illinois ruled, the general duties imposed by Illinois common law do not impose state requirements respecting the device at issue that are "different from, or in addition to," any specific federal requirement. Pet. App. 12-15.

a. The FDA's decision to grant an IDE or a PMA for a medical device does not, by itself, create specific federal requirements within the meaning of Section 360k. We therefore disagree with the Appellate Court on this point. See Pet. App. 13a.

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[6] Although this point reflects a view of the merits, this Court has long recognized that *Cox*'s fourth category frequently requires some inquiry into the merits of the underlying claims. See *Cox Broadcasting*, 420 U.S. at 486 n.13.

The FDA's grant of an IDE signifies that the FDA has examined the manufacturer's application and determined that the device meets the federal criteria for investigatory use. See 21 U.S.C. 360j(g). Similarly, the FDA's grant of a PMA signifies that the FDA has examined the manufacturer's application and determined that the device satisfies the federal criteria for marketing. See 21 U.S.C. 360e(d). The federal criteria are important, and the FDA conducts a careful inquiry to ensure compliance. See 21 C.F.R. Pts. 812 (IDE procedures), 814 (PMA procedures). But in the typical case, the federal criteria for IDEs and PMAs are the generally applicable threshold standards set out in the MDA and the FDA regulations. See 21 C.F.R. 812.30(b) (grounds for denying an IDE), 814.45 (grounds for denying a PMA). As in the case of the premarket notification, labeling, and manufacturing requirements in *Medtronic*, those general criteria establish minimum standards that do not displace state law standards of care or common law duties respecting the medical device.

The FDA may impose specific federal requirements for a Class III device, above and beyond the general federal criteria, that have preemptive force. For example, if the FDA determines that precise design, manufacturing, or labeling specifications are necessary to protect the public, it may impose such requirements through promulgation of specific regulations. See, *e.g.*, 21 C.F.R. 861.1(b)(3) (providing for mandatory performance standards for Class III devices). A manufacturer that seeks an IDE or PMA must satisfy those specific requirements, but they exist independently of the IDE and PMA processes. We have been informed by the FDA that it imposes such specific requirements on Class III devices only in extraordinary situations, and only after it has considered the preemptive consequences of its action under Section 360k. See *Medtronic*, 116 S. Ct. at 2260 (Breyer, J., concurring in part and concurring in the judgment) (the FDA must

consider "the likely impact of both state and federal requirements").

The FDA's differentiation between agency review under the general IDE and PMA criteria and agency imposition of specific substantive requirements reflects its sensible and long-standing approach to regulating medical devices. Under the regulatory scheme, a manufacturer is responsible for submitting an application demonstrating that the proposed medical device satisfies federal minimum standards. See, *e.g.*, 21 C.F.R. Pts. 812, 814. If (as in this case) the FDA has not set out specific federal requirements for the particular device, the manufacturer may select any design, manufacturing, and labeling features that will satisfy the general minimum standards in the Act and regulations, and it may obtain an IDE or PMA on the basis of that selection if the FDA approves the application. Because the FDA has not imposed any specific substantive requirements on petitioner's design of the CVS in the course of the review process, that design does not represent a specific federal requirement that preempts state common law requirements. Cf. *American Airlines, Inc.* v. *Wolens*, 513 U.S. 219, 229 (1995). But if the FDA sets out specific requirements for the particular device in the future, the manufacturer must also satisfy those requirements, which would then preempt any different or additional state requirements.

The FDA's distinction between its review under federal minimum standards and its imposition of specific substantive requirements is consistent with the MDA's underlying objective of promoting safe and effective medical devices. For example, the FDA's grant of a PMA under the statutory criteria provides assurance, but not a guarantee, that the device is safe and effective for its specified use. Where the FDA has taken no further action, the States are entitled to exercise their historic police powers to provide their citizens with additional protec-

tion through positive enactments or through imposition of common law duties. But where the FDA has specifically identified a need to supplement the generalized minimum standards in the Federal Act and FDA regulations with additional federal requirements respecting the particular device, those specific requirements should supplant any state requirements that are "different from, or in addition to," the federal requirements. That approach respects the MDA's "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Medtronic*, 116 S. Ct. at 2257.

b. Section 360k is also inapplicable in the circumstances of this case because petitioner has not shown that Illinois common law imposes a substantive requirement specifically with respect to the medical device at issue here.[7] State courts can, of course, refine common law duties in a way that actually imposes specific requirements respecting a particular medical device. For example, a state court could provide, through its rulings or jury instructions, that a particular design feature breaches a common law duty. See *Medtronic*, 116 S. Ct. at 2259 (Breyer, J., concurring in part and concurring in the judgment). But the Illinois courts thus far have not done so in this case, and there accordingly would be no basis at this point for holding that Section 360k necessarily preempts state common law in this case—even if, contrary to our submission in point 2.a, the FDA had imposed a "specific" counterpart requirement with respect to the device. Indeed, the fact that the state courts, in the course

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[7] The same reasoning holds true with respect to respondents' claims that petitioner breached an implied warranty of merchantability under state law. Pet. App. 16. With respect to claims based on any express warranties, the manufacturer's obligations arise from its "express representations, not by a state-imposed duty." *Id.* at 18. They do not involve state "requirements" at all. *Ibid.*

of further proceedings, can refine state common law duties in light of experience and the circumstances of the particular cases, allows those courts to avoid creating conflicts between federal and state requirements that would lead to preemption.

3. As petitioner correctly notes, the lower courts, both state and federal, have not reached a consensus on questions concerning Section 360k's preemption of state common or statutory law applied in tort suits. See Pet. 7-10.[8] The current division among the lower courts on that issue would normally provide a strong justification for this Court to grant review and definitively resolve the conflict. The jurisdictional obstacle noted above (see pages 10-14, *supra*) would, in our view, prevent the Court from taking that action in this case. But even in the absence of that obstacle, we believe that it would be appropriate for the Court to defer review in light of the

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[8] See also, *e.g.*, *Mitchell* v. *Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (preemption of state law claims respecting a device that received a PMA); *Oja* v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) (preemption of state law claims respecting a Class II medical device); *Chambers* v. *Osteonics Corp.*, 109 F.3d 1243 (7th Cir.) (partial preemption of state law claims respecting a device that received an IDE); *Papike* v. *Tambrands, Inc.*, 107 F.3d 737 (9th Cir.) (preemption of state law claims respecting a device that received a PMA), cert. denied, 118 S. Ct. 166 (1997); *Martin* v. *Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997) (preemption of state law claims respecting a device that received an IDE), petition for cert. pending, No. 96-1749 (filed May 1, 1997); *Fry* v. *Allergan Medical Optics*, 695 A.2d 511 (R.I.) (preemption of state law claims respecting a device that received a PMA), cert. denied, 118 S. Ct. 374 (1997); *Fiore* v. *Collagen Corp.*, 930 P.2d 477 (Ct. App. 1996) (no preemption of state law claims respecting a device that received a PMA), review denied, No. CV-96-0447-PR (Ariz. Jan. 14, 1997), petition for cert. pending, No. 96-1611 (filed Apr. 10, 1997); *Eddy* v. *Polymer Technology Corp.*, 674 A.2d 323 (Super. Ct. 1995) (Table) (preemption of state law claims), appeal denied, 692 A.2d 566 (Pa. 1997) (Table), petition for cert. pending, No. 97-26 (filed June 30, 1997).

FDA's recent initiative to provide an interpretive rule on Section 360k's preemptive effect.

This Court concluded in *Medtronic* that the FDA's views should be given "substantial weight" in determining the reach of the MDA's preemption clause. 116 S. Ct. at 2256. As the Court explained, "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect," because "in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal 'requirement.'" *Id.* at 2255. "Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Ibid.* (footnote omitted) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)); see also *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment).

The FDA will issue, for notice and comment, a proposed interpretive rule providing guidance on Section 360k's preemptive effect with respect to product liability claims under state law. That proposed rule explains that, as a general matter, a state common law duty is preempted only when: (1) the FDA has expressly imposed, by regulation or order, a specific substantive requirement applicable to a particular medical device; and (2) state common law imposes a substantive requirement applicable to the same medical device that is different from, or in addition to, the FDA's counterpart requirement. See App., *infra*, 1a-18a.

Under the FDA's interpretation, MDA minimum standards that are generally applicable to medical devices will typically not result in preemption of state tort claims. Accordingly, the FDA's grant of an IDE or a PMA does not, by itself, have preemptive effect. If the FDA imposes,

however, a substantive requirement for a particular medical device (such as a mandatory standard of performance, see 21 C.F.R. 861.1), that requirement would preempt a specific substantive requirement imposed by state statute, regulation, or common law (as interpreted and applied) that is "different from, or in addition to," the federal requirement. 21 U.S.C. 360k(a).

The FDA will publish its interpretive regulation for notice and comment on December 12, 1997, and it may modify and refine it in response to public comment before issuing it in final form. Furthermore, although the FDA's guidance is entitled to "substantial weight," it will not bind the lower courts. Nevertheless, the FDA's regulation is likely to focus the judicial inquiry and reduce the current uncertainty respecting Section 360k's preemptive effect. We therefore suggest that the Court should allow the lower courts to consider the scope of Section 360k in light of the FDA's regulation before the Court undertakes review of issues that it left open in *Medtronic*.[9]

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

SETH P. WAXMAN
Solicitor General
FRANK W. HUNGER
Assistant Attorney General
DOUGLAS N. LETTER
THOMAS M. BONDY
Attorneys

DECEMBER 1997

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[9] The President recently signed amendments to the FDCA that, *inter alia*, expedite the process for reviewing and approving PMA and IDE applications. See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, §§ 201, 209, 111 Stat. 2296. Those amendments make no changes to the MDA's preemption provision.

APPENDIX

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 808

[Docket No. 97N-0222]

Medical Devices; Preemption of State Product Liability Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations regarding preemption of State and local requirements applicable to medical devices. This action is being taken to clarify and codify the agency's longstanding position that available legal remedies, including State common law tort claims, generally are not preempted under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Written comments by (*insert 60 days after date of publication in* **Federal Register**).

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health

(HFZ-215), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-827-2974.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 521 of the act (21 U.S.C. 360k) contains an express preemption provision applicable to medical devices regulated by FDA. The Supreme Court recently addressed whether section 521 of the act preempts State common law tort claims arising from allegedly defective medical devices. (See *Medtronic, Inc.* v. *Lohr (Lohr)*, 116 S. Ct. 2240 (1996).) The Court concluded that section 521 of the act did not supplant the State law duties at issue in that case. In reaching that conclusion, the Court noted that FDA has provided interpretive guidance with respect to section 521 of the act's preemptive effect. (See *id.* at 2255-2256 (citing 21 CFR 808.1(d)(2) and 808.5(b)(1)(i) (1995)).) The Court gave "substantial weight to the agency's view of the statute" (*Id.* at 2256). (See also *id.* at 2257; *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment).)

The Court's decision in *Lohr* construed section 521 of the act in the context of a medical device that FDA had cleared for distribution under section 510(k) of the act (21 U.S.C. 360k), which requires premarket notification for certain types of medical devices. The Court did not definitively decide whether section 521 of the act may preempt State law claims in other circumstances. Since *Lohr* was decided, the lower courts have interpreted section 521 of the act inconsistently and have reached conflicting conclusions with respect to whether section 521 of the act preempts State law claims for injuries allegedly resulting from medical devices that have received premarket approval under section 515 of the act (21 U.S.C. 360e), or have

received an investigational device exemption (IDE) under section 520(g) of the act (21 U.S.C. 360j(g)).

In light of the confusion among the lower courts in interpreting section 521 of the act since *Lohr*, and in accordance with the Supreme Court's recognition that FDA's interpretation of the preemptive effect of section 521 of the act is entitled to substantial weight, the agency is issuing this proposed interpretive rule, which addresses the circumstances in which section 521 of the act preempts State common tort claims based on injury from allegedly defective medical devices.

II. Background

Congress enacted the Medical Device Amendments of 1976 (the amendments) (21 U.S.C. 360c *et seq.*) "to provide for the safety and effectiveness of medical devices intended for human use." It enacted the amendments largely in response to public concerns over injuries caused by medical products, such as the Dalkon Shield intrauterine device. (See S. Rept. No. 33, 94th Cong., 1st sess. 1 (1975); H. R. Rept. No. 853, 94th Cong., 2d sess. 8 (1976); 122 Congressional Record 13,779 (1976)). Congress sought "to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions" (H. R. Rept. No. 853, *supra*, at 12).

Section 521 of the act was included as part of the amendments, and generally states that except as provided in section 521(b) of the act no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement which is different from, or in addition to, any Federal requirement

applicable to the device, and which relates to the safety or effectiveness of the device or to any other matter included in a Federal requirement applicable to the device.

Section 521(b) sets forth the requirements if a political subdivision thereof applies for an exemption from a Federal requirement. The Secretary may issue a regulation to exempt from section 521(a) of the act, under conditions prescribed in the regulation, if the requirement is more stringent than the Federal requirement which would be applicable to the device if an exemption were not in effect or the requirement is required by compelling local conditions, and compliance with the requirement would not cause the device to be in violation of any applicable Federal requirement under this chapter.

FDA has interpreted the preemptive scope of section 521 of the act in light of its specific language and Congress's expressed objectives. Section 521(a) forbids a State from subjecting a medical device to any "requirement" that is "different from, or in addition to," any Federal requirement imposed under the act; and relates to "the safety or effectiveness of the device" or to "any other matter" included in the Federal requirement. FDA has indicated, through regulations that have been in place since 1978, that section 521 of the act's preemptive effect is limited in light of the section's precise terminology and Congress's declared intention to promote the safety and effectiveness of medical devices. (See 21 CFR 808.1.)

When FDA issued its 1978 regulations, the regulated community was primarily interested in the effect of section 521 of the act on State or local requirements that were expressed through positive enactments, such as statutes or regulations. FDA's regulations addressed the question of preemption in that general context. Section 808.1(d), which has remained substantially unchanged for

nearly 20 years, states that State or local requirements are preempted only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific FDA requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act.

FDA's regulations (§ 808.1) provide nine examples of State or local provisions that are not preempted, including:

(1) Generally applicable requirements not limited to medical devices (e.g., general electrical codes and the Uniform Commercial Code (warranty of fitness));

(2) Requirements that are equal to or substantially identical to requirements imposed by or under the act;

(3) Occupational licensing requirements;

(4) Specifications in government contracts for the procurement of devices;

(5) Criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health care programs;

(6) General enforcement requirements, including State inspection and registration requirements, or a State or local prohibition against the manufacturer of adulterated or misbranded devices (except where the prohibition, as interpreted and enforced, has the effect of establishing a substantive requirement for a specific device);

(7) Provisions respecting delegations of authority and related administrative matters respecting devices;

(8) Fee and other revenue raising requirements; and

(9) State or local requirements issued under the authority of other Federal statutes.

In 1992, the Supreme Court decided *Cippolone* v. *Liggett Group, Inc.* (505 U.S. 504 (1992)). Among other things, the Court ruled in that case that section 5(b) of the Public Health Cigarette Smoking Act of 1969 (15 U.S.C. 1334(b)) could preempt State common law suits alleging that the manufacturers breached their duty to warn about hazards associated with smoking. Section 5(b) states that no requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

A majority of the Supreme Court concluded that the phrase "[n]o requirement or prohibition," as used in that statute, describes both positive enactments and common law duties. (See 505 U.S. at 521 (opinion of Stevens, J.); *id.* at 548-549 (Scalia, J., concurring in the judgment in part and dissenting in part).)

After the Supreme Court's decision in *Cippolone*, a number of lower courts interpreted section 521 of the act to preempt tort actions respecting allegedly defective medical devices in which the plaintiff sought to hold the manufacturer liable based on State common law. Those courts found preemption in a variety of contexts, including situations in which FDA had allowed marketing of the device after "premarket notification" under section 510(k) of the act (21 U.S.C. 360(k)), (e.g., *Mendes* v. *Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994)); in which FDA had granted premarket approval of the device under section 515 of the act (21 U.S.C. 360e), (e.g., *King* v. *Collagen Corp.*, 983 F.2d

1130 (1st Cir.) *cert. denied*, 510 U.S. 824 (1993)); and in which FDA had granted an IDE under section 520(g) of the act (21 U.S.C. 360j(g)), (e.g., *Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992)).

The Supreme Court addressed the scope of section 521 of the act's preemptive effect in *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996). That case arose out of Medtronic's marketing of a cardiac pacemaker that FDA found was "substantially equivalent" to a medical device already on the market and that was therefore subject to the premarket notification requirements of section 510(k) of the act (21 U.S.C. 360(k)). The plaintiffs alleged that they were injured by the device and sought damages under Florida common law. They asserted that Medtronic breached its common law duty "to use reasonable care in the design, manufacture, assembly, and sale of the subject pacemaker" and that Medtronic was strictly liable because the device "was in a defective condition and unreasonably dangerous to foreseeable users at the time of its sale" (116 S. Ct. at 2248).

The Court concluded that section 521 of the act did not preempt the plaintiffs' negligent design claim. It specifically rejected Medtronic's contention that the company's compliance with its statutory obligation to demonstrate through the premarket notification process that the pacemaker was "substantially equivalent" to a preexisting device preempted those claims (116 S. Ct. at 2254-2255). The Court noted that, when FDA reviews a device under the premarket notification provisions, it does so with "a concern for the safety and effectiveness of the device" (*id.* at 2254), but that FDA "did not 'require' Medtronics' pacemaker to take any particular form for any particular reason" (*ibid*). Rather, FDA simply allowed Medtronic

to market the pacemaker based on the article's equivalence to the preexisting device (*Id.* at 2254-2255). The Supreme Court was unanimous on this point, since Justice O'Connor's separate opinion for four Justices agreed that the section 510(k) premarket notification process "places no 'requirement' on a device" and therefore does not preempt a defective design claim (*Id.* at 2264).

The Court also concluded that section 521 of the act did not preempt the plaintiffs' State law claims that Medtronic had violated FDA requirements (116 S. Ct. at 2255-2256). The Court reasoned that State common law claims premised on Medtronic's failure to comply with FDA requirements do not subject the manufacturer to requirements that are "different from, or in addition to," the Federal requirements (*Id.* at 2255). The Court noted that FDA's interpretive regulations "expressly support the conclusion that [section 521] 'does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.'" (*Id.* at 2256 (quoting 21 CFR 808.1(d)(2) (1995))). It also observed that FDA's views on the scope of section 521 of the act's preemptive effect are entitled to "substantial weight." (*Ibid*).

The Court additionally concluded that section 521 of the act did not preempt the plaintiffs' State law claims based on negligent manufacturing and labeling (116 S. Ct. at 2256-2258). The Court recognized that FDA had developed regulations that set out general "requirements" for manufacturing and labeling medical devices (*Id.* at 2256). It concluded, however, that section 521 generally does not mandate preemption of a standard of care under State common law unless, as FDA had suggested in its interpretive regulations, FDA has issued "specific counterpart regulations or * * * other specific requirements

applicable to a particular device" (*Id.* at 2257 (quoting 21 CFR 808.1(d) (1995))). The Court concluded that the "entirely generic" Federal requirements did not provide a basis for preemption of the nonspecific State common law duties at issue in that case (*Id.* at 2258). Justice Breyer, agreeing with Justice O'Connor's opinion (see *id.* at 2262-2263), concluded that, insofar as the act preempts a State requirement embodied in a statute or regulation, it also preempts a similar State requirement that takes the form of a standard of care imposed by State tort law (*id.* at 2259-2260) but he concurred in the Court's holding that manufacturing and labeling requirements issued by FDA were not sufficiently specific to trigger preemption (*id.* at 2260-2261).

Since the Supreme Court's decision in *Lohr*, the lower courts have continued to reach contradictory determinations respecting section 521 of the act's preemptive effect, particularly as it relates to medical devices that have received premarket approval or an investigatory device exemption. Compare, e.g., *Fry* v. *Allergan Medical Optics*, 695 A.2d 511 (R.I. 1997) (finding preemption), *cert. denied*, No. 97-513 (U.S. Sup. Ct., Nov. 3, 1997) with *Kernats* v. *Smiths Indus. Med. Sys., Inc.*, 669 N.E. 2d 1300 (Ill. App. Ct.) (finding no preemption), *appeal denied*, 675 N.E.2d (Ill. 1996), *petition for cert. pending*, No. 96-1405 (U.S. Sup. Ct., filed Mar. 4. 1997).

III. The Proposed Rule

FDA interprets section 521 of the act's preemptive effect on the basis of congressional intent. As the Supreme Court stated in *Lohr*, congressional purpose "is the ultimate touchstone" in every preemption case, and "a fair understanding of congressional purpose" may be discerned not only from the text of the statute, but also through a "reasoned understanding of the way in which Congress

intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law" (116 S. Ct. at 2250-2251 (emphasis deleted)). In addition, the statutory text must be read in light of established presumptions respecting preemption. As the Supreme Court stated in *Lohr*, the States are presumed to retain their historic police powers unless Congress expresses a "clear and manifest purpose" to supersede those powers (*Id.* at 2250).

Section 521 of the act does not, as a general matter, prevent a party who is injured by a defective medical device from seeking redress under a State's common law. Rather, section 521(a) of the act provides that a State may not "establish or continue in effect with respect to a device" a "requirement" that is "different from, or in addition to," a "requirement applicable under this chapter to the device" that "relates to the safety or effectiveness of the device" or to "any other matter included in" the Federal requirement (21 U.S.C. 360k(a)). By its plain terms, section 521 of the act does not prevent a State from imposing common law duties on manufacturers of medical devices unless those duties are "requirements" of the kind described in the statute.

When FDA articulated its understanding of section 521 of the act in its 1978 regulations, it stated the general rule to be that "State or local requirements are preempted only when the agency has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements" (§ 808.1(d)). The Supreme Court explicitly endorsed FDA's position in the *Lohr* decision. (See 116 S.

Ct. at 2257; *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment)). Similarly, the 1978 regulations provide that section 521 of the act does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices, but that where such a prohibition, as "interpreted and enforced by the State and local government," "has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement," it will be preempted if it is different from, or in addition to, a specific requirement established by FDA for the device (§ 808.1(d)(6)(ii)).

In 1978, FDA stated its understanding of section 521 of the act in the general context of State requirements that are imposed through positive law, such as statutes or regulations. The same principles should govern, however, in the case of State requirements that are imposed through the common law. FDA has consistently concluded that the same principles govern when it has addressed the question of preemption through its regulations, advisory opinions, and its judicial filings as amicus curiae. The Supreme Court implicitly endorsed that conclusion in the *Lohr* decision by applying the principles that FDA has announced in its 1978 regulations to the Lohrs' common law suit (See 116 S. Ct. at 2255-2256, 2257-2258; *id.* at 2260-2261 (Breyer, J., concurring in part and concurring in the judgment in part)).

In accordance with the principles that FDA articulated in its 1978 regulations, to which the Supreme Court in *Lohr* held that deference is owed, FDA believes that, as a general matter, an FDA-imposed requirement will preempt a State common law duty only when: (1) FDA has expressly imposed, by regulation or order, a specific substantive requirement applicable to a particular medical

device; and (2) the State common law, as interpreted and applied, imposes a substantive requirement applicable to the same particular medical device that is different from, or in addition to, FDA's counterpart requirement. Under this approach, FDA requirements that are applicable to devices in general, or that are established by means other than through regulation or order, should generally not result in preemption of State tort claims.

FDA bases its interpretation primarily on the language of section 521 of the act and the agency's past regulatory interpretation set out in § 808.1. In addition, a plurality of the Court noted in *Lohr* that there is no indication in the legislative history of the amendments that Congress intended to make a "dramatic change" in the availability of State common law remedies (*Id.* at 2253 n.13 (opinion of Stevens, J.)). The legislative history indicates that Congress was aware of ongoing product liability suits involving medical devices, but it contains no indication that Congress intended that the amendments would preempt those suits. See, e.g., S. Rept. No. 33, *supra*, at 1; H. R. Rept. No. 853, *supra*, at 8; 121 Congressional Record 10,688 (1975) (Sen. Kennedy); *id.* at 10,689 (Sen. Nelson); 122 Congressional Record 5850 (1976) (Rep. Abzug).

FDA's interpretation is also founded in its experience and understanding gained through implementing the amendments. FDA believes that its general regulatory review and approval processes provide a significant measure of protection against the marketing of dangerous or defective medical devices. FDA does not believe, however, that those processes can guarantee the safety of such devices. Accordingly, compliance with general FDA requirements should not broadly preempt State common law remedies, which provide an important (and frequently the

only) mechanism for persons to seek redress for injuries resulting from defective medical devices. FDA notes below several situations in which the agency's regulatory activities will typically not preempt State law remedies.

First, FDA's general clearance and approval processes, such as the clearance for marketing under section 510(k) of the act; the grant premarket approval under section 515 of the act; or the grant of an IDE under section 520(g) of the act, do not, by themselves, preempt State common law claims. Section 521 of the act provides for preemption of a State common law duty only if it imposes a requirement that is different from, or in addition to, a specific substantive requirement pertaining to the particular device that has been imposed by or under the act. FDA's action in clearing a product for marketing or granting an application for a PMA or an IDE signifies that the manufacturer's proposal for marketing or use of the device in question satisfies the relevant statutory and regulatory criteria for the clearance, approval, or exemption. It does not signify, however, that Congress or FDA has established a specific Federal requirement (e.g., with respect to the design of the device) that supplants a State common law duty.

Second, FDA's notification of deficiencies in, or proposal of modifications to, an application for a PMA or an IDE does not, as a general matter, create specific Federal requirements that have preemptive effect. Under FDA's approval and exemption programs, the applicant bears responsibility for preparing an acceptable application. FDA may notify the applicant of deficiencies and propose modifications to ensure that the applicant has satisfied the minimum standards for FDA approval or exemption, but those actions do not relieve the applicant of its ultimate responsibility for proposing the design, manufacturing,

and labeling of the device. For purposes of preemption analysis, the applicant who modifies an application in response to an agency notification of deficiency or proposal for modification has simply achieved the same status as an applicant who had submitted a satisfactory application at the outset.

Third, as the Supreme Court concluded in *Lohr*, FDA's general requirements respecting labeling (21 CFR 801.1 through 801.16), and good manufacturing practices (21 CFR 820.1 through 820.198), do not preempt State requirements, because the general Federal requirements do not pertain to specific devices. (See *Lohr*, 116 S. Ct. at 2256-2258). The same controlling principle applies whether the device subject to those requirements is a "grandfathered" device that was marketed before the enactment of the amendments, received FDA clearance for marketing under section 510(k) of the act, received a PMA under section 515 of the act, or received an IDE under section 520(g) of the act.

Fourth, even if FDA has imposed specific Federal requirements respecting a particular medical device, those requirements do not preempt all State common law claims respecting the device. Section 521 of the act provides for preemption only if the State common law duties are "different from, or in addition to," the specific Federal requirements. In many cases, preemption will depend on the plaintiff's precise legal claims and theories of recovery. For example, as the Supreme Court noted in *Lohr*, if the State common law required the manufacturer to comply with the Federal requirements, section 521 of the act would not preempt that duty (116 S. Ct. at 2255-2256). Furthermore, the courts may be able to reconcile an apparent conflict between Federal and State requirements by, for example, carefully formulating jury instructions to

limit the bases for liability to substantive standards of care that are consistent with any specific requirement that FDA has made applicable to the device.

In every case, section 521 of the act's preemptive effect should be evaluated in light of the statute's precise terms. As the Supreme Court noted in *Lohr*, section 521 of the act and FDA's regulations "require a careful comparison between the allegedly preempting Federal requirement and the allegedly preempted State requirement to determine whether they fall within the intended preemptive scope of the statute and regulations" (116 S. Ct. at 2257-2258). The outcome of particular cases will frequently depend on the character and circumstances of the particular state law claim. FDA will continue to monitor the development of the law in this area and provide additional guidance as the need arises.

This proposed rule would make no change in the agency's prior or current construction of the scope of section 521 of the act. Rather, the rule would simply clarify and codify the agency's longstanding interpretation of the scope of section 521 of the act as generally not preempting available legal remedies, including State common law tort claims.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule only interprets the statute and does not establish any requirements, the agency certifies that this proposed rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Request for Comments

Interested persons may, on or before (*insert date 60 days after date of publication in the* **Federal Register**), submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be

seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 808

Intergovernmental relations, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 808 be amended as follows:

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICES REQUIREMENTS

1. The authority citation for 21 CFR part 808 continues to read as follows:

Authority: 21 U.S.C. 360j, 360k, 371.

2. Section 808.1 is amended by adding new paragraphs (d)(11) and (d)(12) to read as follows:

§ 808.1 Scope.

* * * * *

(d) * * *

(11)(i) An FDA imposed requirement will preempt a State common law duty only when:

(A) FDA has expressly imposed, by regulation or order, a specific substantive requirement applicable to a particular device; and

(B) The State common law, as interpreted and applied, imposes a substantive requirement applicable to the same particular device that is different from, or in addition to, FDA's counterpart requirement.

(ii) FDA requirements that are applicable to devices in general, or that are established by means other than through regulation or order, should not result in preemption of State tort claims.

(12) The clearance or approval of a particular device for marketing under section 510(k), 515, or 520(g) of the act does not in itself constitute the imposition of a specific substantive requirement with respect to that particular device that preempts a State or local requirement, including a standard of care imposed under State common law, with respect to the same device.

Dated: December 8, 1997

/s/ WILLIAM B. SCHULTZ
WILLIAM B. SCHULTZ